LEGISLATURE OF THE STATE OF IDAHO

Sixtieth Legislature First Regular Session - 2009

IN THE SENATE

SENATE BILL NO. 1066

BY HEALTH AND WELFARE COMMITTEE

AN ACT

RELATING TO THE IDAHO WHOLESALE DRUG DISTRIBUTION ACT; AMENDING SECTION 54-1752, IDAHO CODE, TO REVISE A DEFINITION AND TO MAKE A TECHNICAL CORRECTION; AMENDING SECTION 54-1755, IDAHO CODE, TO REVISE THE CONTENTS OF A PEDIGREE; AND DECLARING AN EMERGENCY.

Be It Enacted by the Legislature of the State of Idaho:

SECTION 1. That Section 54-1752, Idaho Code, be, and the same is hereby amended to read as follows:

54-1752. DEFINITIONS. As used in sections 54-1751 through 54-1759, Idaho Code:

(1) "Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(2) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in section 1504 of the Internal Revenue Code, complies with the following:

(a) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and

(b) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

(3) "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership and control.

(4) "Colicensed partner or product" means an instance where two (2) or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with the federal food and drug administration's implementation of the prescription drug marketing act.

(5) "Drop shipment" means the sale of a prescription drug to a wholesale distributor or chain pharmacy warehouse by the manufacturer of the prescription drug, or that manufacturer's colicensed product partner, that manufacturer's third party logistics provider or that manufacturer's exclusive distributor, whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug and the wholesale distributor invoices the pharmacy or chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from

the manufacturer, or that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor.

(6) "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged or offered for sale.

(7) "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the federal food and drug administration definition of "manufacturer" under its regulations and guidance implementing the prescription drug marketing act.

(8) "Manufacturer's exclusive distributor" means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. Such manufacturer's exclusive distributor must be licensed as a wholesale distributor under section 54-1753, Idaho Code, and to be considered part of the normal distribution channel, must also be an authorized distributor of record.

(9) "Normal distribution channel" means a chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's colicensed partner, from that manufacturer to that manufacturer's ~~third party~~ third party logistics provider, ~~or~~ from that manufacturer to that manufacturer's exclusive distributor, or from that manufacturer directly or through its colicensed partner, third party logistics provider or manufacturer's exclusive distributor to a repackager who is an authorized distributor of record for the manufacturer, whose facility is registered with the United States food and drug administration and who engages in the practice of repackaging the original dosage form of a prescription drug in accordance with applicable regulations and guidelines of the United States food and drug administration, either directly or by drop shipment, to:

(a) A pharmacy to a patient;

(b) Other designated persons authorized by law to dispense or administer such drug to a patient;

(c) A wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(d) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or

(e) A chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient.

(10) "Pedigree" means a document or electronic file containing information that records each wholesale distribution of any given prescription drug.

(11) "Prescription drug" means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law or federal regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances, subject to section 503(b) of the federal food, drug and cosmetic act.

(12) "Repackage" means repackaging or otherwise changing the container, wrapper or labeling to further the distribution of a prescription drug, excluding that completed by the pharmacist responsible for dispensing product to the patient.

(13) "Repackager" means a person who repackages.

(14) "Third party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. Such third party logistics provider must be licensed as a wholesale distributor under section 54-1753, Idaho Code, and to be considered part of the normal distribution channel, must also be an authorized distributor of record.

(15) "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs including, but not limited to:

(a) Manufacturers;
(b) Repackagers;
(c) Own-label distributors;
(d) Private-label distributors;
(e) Jobbers;
(f) Brokers;
(g) Warehouses, including manufacturers' and distributors' warehouses;
(h) Manufacturer's exclusive distributors;
(i) Authorized distributors of record;
(j) Drug wholesalers or distributors;
(k) Independent wholesale drug traders;
(l) Specialty wholesale distributors;
(m) Third party logistics providers;
(n) Retail pharmacies that conduct wholesale distribution; and
(o) Chain pharmacy warehouses that conduct wholesale distribution.

To be considered part of the normal distribution channel, such wholesale distributor, except for a chain pharmacy warehouse not engaged in wholesale distribution, must also be an authorized distributor of record.

(16) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between colicensees of a colicensed product.

(b) The sale, purchase, distribution, trade or transfer of a prescription drug or offer to sell, purchase, distribute, trade or transfer a prescription drug for emergency medical reasons.

(c) The distribution of prescription drug samples by manufacturers' representatives.

(d) Drug returns, when conducted by a hospital, health care entity or charitable institution in accordance with 21 CFR 203.23.

(e) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use.

(f) The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription.

(g) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

(h) The sale, purchase, distribution, trade or transfer of a prescription drug from one (1) authorized distributor of record to one (1) additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had, until that time, been exclusively in the normal distribution channel.

(i) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, and such common carrier does not store, warehouse or take legal ownership of the prescription drug.

(j) The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned or recalled prescription drugs to the original manufacturer or third party returns processor, including a reverse distributor.

SECTION 2. That Section 54-1755, Idaho Code, be, and the same is hereby amended to read as follows:

54-1755. PEDIGREE. (1) In General. Each person who is engaged in wholesale distribution of prescription drugs, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, that leaves, or has ever left, the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such drug.

(a) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.

(b) The board shall determine by July 1, 2009, a targeted implementation date for electronic track and trace pedigree technology. Such a determination shall be based on consultation with manufacturers, distributors and pharmacies responsible for the sale and distribution of prescription drug products in this state. After consultation with interested stakeholders and prior to implementation of the electronic pedigree, the board shall deem that the technology is universally available across the entire prescription pharmaceutical supply chain. The implementation date for the mandated electronic track and trace pedigree technology will be no sooner than July 1, 2010, and may be extended by the board in one (1) year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.

(2) Authentication. Each person who is engaged in the wholesale distribution of a prescription drug, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, who is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug, shall affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(3) Contents. The pedigree shall:

(a) Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, or the manufacturer's third party logistics provider, colicensed product partner, ~~or~~ manufacturer's exclusive distributor, or a repackager who is an authorized distributor of record for the manufacturer, whose facility is registered with the United States food and drug administration and who engages in the

practice of repackaging the original dosage form of a prescription drug in accordance with applicable regulations and guidelines of the United States food and drug administration, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At minimum, the necessary pedigree information shall include:

(i) Name, address, telephone number and, if available, the e-mail address, of each owner of the prescription drug, and each wholesale distributor of the prescription drug;

(ii) Name and address of each location from which the product was shipped, if different from the owner's;

(iii) Transaction dates; and

(iv) Certification that each recipient has authenticated the pedigree.

(b) At minimum, the pedigree shall also include the:

(i) Name of the prescription drug;

(ii) Dosage form and strength of the prescription drug;

(iii) Size of the container;

(iv) Number of containers;

(v) Lot number and national drug code number of the prescription drug; and

(vi) Name of the manufacturer of the finished dosage form.

(4) Maintenance Provisions. Each pedigree or electronic file shall be:

(a) Notwithstanding the provisions in section 54-1735, Idaho Code, maintained by the purchaser and the wholesale distributor for not less than three (3) years from the date of sale or transfer; and

(b) Available for inspection or use within five (5) business days upon a request of an authorized officer of the law.

(5) Implementation. The board shall adopt rules and a form relating to the requirements of this section no later than ninety (90) days after the effective date of this act.

SECTION 3. An emergency existing therefor, which emergency is hereby declared to exist, this act shall be in full force and effect on and after its passage and approval.